

ANDREA RACHELLE CLINTON,  
Plaintiff,  
vs.  
MENTOR WORLDWIDE LLC,  
Defendant.

This matter is before the Court on plaintiff's and defendant's motions to exclude expert evidence, filed pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Additionally, plaintiff has filed a motion to enforce prior *Daubert* orders [Doc. #112] entered by the MDL court. The parties have responded to the motions, and the issues are fully briefed.

This case arises out of the injuries allegedly sustained by the plaintiff, Andrea Rachelle Clinton, from the implantation of a suburethral sling product called ObTape Transobturator Tape (ObTape). On December 2, 2004, plaintiff underwent surgical implantation of ObTape for treatment of stress urinary incontinence. Defendant Mentor Worldwide LLC is the developer of ObTape. In December 2007, plaintiff was diagnosed with an infection of the ObTape mesh and was advised that she needed to undergo revision surgery to treat the infection. The revision surgery was performed on December 24, 2007, during which the doctor removed as much of the ObTape as possible. A second revision surgery was performed on February 5, 2008

in order to identify and remove additional ObTape. A third revision surgery was performed on February 27, 2008; however the doctor was unable to find any additional tape. A fourth and final revision surgery was performed on March 21, 2008, and additional infected portions of the ObTape were removed.

In the complaint, plaintiff asserts the following claims: (1) negligence (2) strict liability–design defect; (3) strict liability-manufacturing defect; (4) strict liability-failure to warn; (5) breach of implied warranty; (6) breach of express warranty; (7) fraudulent misrepresentation; (8) fraudulent concealment; and (9) negligent misrepresentation. [Doc. #1]. Plaintiff’s breach of express warranty and continuing duty to warn claims were dismissed at the summary judgment stage. [Doc. #67].

## **II. Legal Standard**

The admission of expert testimony in federal courts is governed by Federal Rule of Evidence 702, which provides that a court may permit opinion testimony from a witness qualified as an expert if: “(a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based upon sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.” Fed. R. Evid. 702. The Eighth Circuit has summarized the inquiry under Rule 702 as follows:

First, evidence based on scientific, technical, or other specialized knowledge must be useful to the finder of fact in deciding the ultimate issue of fact. This is the basic rule of relevancy. Second, the proposed witness must be qualified to assist the finder of fact. Third, the proposed evidence must be reliable or trustworthy in an

evidentiary sense, so that, if the finder of fact accepts it as true, it provides the assistance the finder of fact requires.

*Johnson v. Mead Johnson & Co., LLC*, 754 F.3d 557, 561 (8th Cir.2014) (quoting *Poliski v. Quigley Corp.*, 538 F.3d 836, 839 (8th Cir.2008)). The focus of the inquiry under Rule 702 is “solely on principles and methodology, not on the conclusions that they generate.” *Daubert*, 509 U.S. at 594–95. “The proponent of the expert testimony must prove its admissibility by a preponderance of the evidence.” *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 686 (8th Cir.2001) (citing *Daubert*, 509 U.S. at 592).

Under Rule 702, district courts act as gatekeepers, ensuring that expert testimony is “not only relevant, but reliable.” *Daubert*, 509 U.S. at 589; see also *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999) (quoting *Daubert*, 509 U.S. at 597). In *Daubert*, the Supreme Court outlined four non-exclusive factors that the district court may look to in evaluating the reliability of expert testimony: (1) whether the scientific technique can be or has been tested; (2) whether the theory or technique has been subjected to peer review or publication; (3) the known rate of error for the technique or theory and the applicable standards for operation; and (4) whether the technique is generally accepted. *Johnson*, 754 F.3d at 562 (citing *Daubert*, 509 U.S. at 593–94). *Daubert*'s progeny provide additional factors such as: “whether the expertise was developed for litigation or naturally flowed from the expert's research; whether the proposed expert ruled out other alternative explanations; and whether the proposed expert sufficiently connected the proposed testimony with the facts of the case.” *Lauzon*, 270 F.3d at 687. As the Supreme Court explained in *Kumho Tire Company*, “the test of reliability is ‘flexible,’ and *Daubert*'s list of specific factors neither necessarily nor exclusively

applies to all experts or in every case. Rather, the law grants a district court the same broad latitude when it decides *how* to determine reliability as it enjoys in respect to its ultimate reliability determination.” 526 U.S. at 141–42. The Eighth Circuit has described the standard in *Daubert* as calling for the “liberal admission” of expert testimony. *Johnson*, 754 F.3d at 562.

“Regardless of what factors are evaluated, the main inquiry is whether the proffered expert’s testimony is sufficiently reliable.” *First Union Nat. Bank v. Benham*, 423 F.3d 855, 861 (8th Cir.2005). The Eighth Circuit has admonished district courts “not to weigh or assess the correctness of competing expert opinions.” *Johnson*, 754 F.3d at 562. As long as the expert’s testimony “rests upon ‘good grounds, based on what is known’ it should be tested by the adversary process with competing expert testimony and cross-examination, rather than excluded by the court at the outset.” *Id.* (quoting *Daubert*, 509 U.S. at 590, 596; *Nebraska Plastics, Inc. v. Holland Colors Americas, Inc.*, 408 F.3d 410, 416 (8th Cir.2005) (“As a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination.” (quoting *Hartley v. Dillard’s, Inc.*, 310 F.3d 1054, 1061 (8th Cir.2002))). “Only if the expert’s opinion is so fundamentally unsupported that it can offer no assistance to the jury must such testimony be excluded.” *Benham*, 523 F.3d at 862. “Doubts regarding ‘whether an expert’s testimony will be useful should generally be resolved in favor of admissibility.’” *Clark v. Hendrick*, 150 F.3d 912, 915 (8th Cir.1998) (quoting *Larabee v. MM & L Int’l Corp.*, 896 F.2d 1112, 1116 n.6 (8th Cir.1990)).

### **III. Discussion**

### **A. Plaintiff's Motions to Exclude**

The plaintiff moves to exclude or limit the opinions and testimony of Gonzalo R. Ballon-Landa, M.D. [Doc. #104], Marjorie Jeffcoat, D.M.D., [Doc. #106], and Ruby Skinner, M.D. [Doc. #113].

#### **Gonzalo R. Ballon-Landa, M.D.**

Defendant designated Dr. Ballon-Landa to rebut conclusions that ObTape caused plaintiff's infections, abscess formation, necrotizing fasciitis and need to undergo extensive, successive operative procedures and that her infection did not originate from the ObTape sling. Dr. Ballon-Landa opines that several significant events of physical trauma led to the development of the necrotizing fasciitis in plaintiff's left leg which led to the development of subclinical hematomas in the region of the left thigh obturator muscles. Plaintiff presents four areas in which she believes Dr. Ballon-Landa's testimony should be excluded or, in the alternative, limited based on unreliability.

Evidence is relevant in a case if "it has any tendency to make a fact more or less probable than it would be without the evidence" and "the fact is of consequence in determining the action." Fed. R. Evid. 401. Dr. Ballon-Landa's report and testimony offers the opinion that plaintiff's initial left thigh infection did not originate with her ObTape but was instead caused by bacteria from her mouth. [Doc. #105-1 and #105-2]. The opinion testimony would be helpful to a jury in deciding whether the plaintiff's injuries were caused by ObTape or whether there was an alternative cause. As such Dr. Ballon-Landa's opinions are relevant to this claim.

#### **1. Thigh Trauma**

Plaintiff first challenges Dr. Ballon-Landa's expert testimony regarding thigh trauma, arguing that his opinion is unreliable because it is based on insufficient facts and speculation. Testimony is unreliable under Rule 702 and should be excluded when expert testimony is speculation upon which there is no reasonable factual basis for the expert opinion. *Weisgram v. Marley Co.*, 169 F.3d 514, 520 (8th Cir.1999), *aff'd*, 528 U.S. 440 (2000). As a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination. *Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 929–30 (8th Cir.2001) (quoting *Hose v. Chicago Northwestern Transp. Co.*, 70 F.3d 968, 974 (8th Cir.1996)). Only if the expert's opinion is so fundamentally unsupported that it can offer no assistance to the jury must such testimony be excluded. *Id.*

Plaintiff argues that expert evidence based on assumptions not supported by the record should be excluded. A certain amount of speculation is necessary, an even greater amount is permissible (and goes to the weight of the testimony), but too much is fatal to admission. *Grp. Health Plan, Inc. v. Philip Morris USA, Inc.*, 344 F.3d 753, 760 (8th Cir.2003). What is required is that when experts "testify in court they adhere to the same standards of intellectual rigor that are demanded in their professional work." *Id.* (quoting *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir.1996) (Posner, J.), *cert. denied*, 519 U.S. 819, (1996)). Dr. Ballon-Landa's opinion regarding the origin of plaintiff's left thigh trauma relies on more than mere speculation. His report notes that the microbiology of the abscess included five bacteria which are commonly found in the mouth. He also notes that there were several episodes of trauma documented in plaintiff's medical records in the time

surrounding the development of her abscess, including an accident on an ATV and an injury suffered at a water park as potential causes. While the medical record contains no reference to any trauma to plaintiff's left thigh after the ATV incident, Dr. Ballon-Landa bases his opinion upon her difficulty walking after the accident despite there being no outward trauma to the left thigh. Plaintiff also reported to her doctor that her left leg was caught in a ride at a water park; however, there is no reference to any trauma to her left thigh following that incident either. [Doc. #117-7-8].

Dr. Ballon-Landa states in his deposition that an infection can be caused by a non-visible, non-obvious trauma. Based upon his experience, an imperceptible trauma is sufficient to cause an infection. The point of Dr. Ballon-Landa's opinion is that necrotizing fasciitis can develop where there is trauma – even in an area where trauma was not immediately apparent – and there are instances in the medical records that would indicate potential trauma to plaintiff's left thigh. Here, plaintiff is challenging the factual basis of Dr. Ballon-Landa's opinion. The record shows that plaintiff was involved in an ATV accident and did suffer injuries from the water park incident. Dr. Ballon-Landa indicates in his report that he examined medical records including reports of the pathology, microbiology and radiology departments plus the physicians and nurse's progress notes, and scholarly literature in developing his expert opinion. "Although it is common that medical experts often disagree on diagnosis and causation, questions of conflicting evidence must be left for the jury's determination." *Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 931 (8th Cir.2001) (quoting *Hose v. Chicago Northwestern Transp. Co.*, 70 F.3d 968, 976 (8th Cir.1996)). Cross-examination is the defendant's opportunity to scrutinize and

question the facts on which Dr. Ballon-Landa based his opinion. *See Hose*, 70 F.3d at 974. Dr. Ballon-Landa's expert report lays out a sufficient factual basis upon which to rest his testimony. Accordingly, plaintiff's motion to exclude Dr. Ballon-Landa's testimony about left thigh trauma will be denied.

## **2. Source of Initial Infection**

Plaintiff further argues that Dr. Ballon-Landa's opinion that ObTape was not the source of the initial infection is unreliable. Dr. Ballon-Landa bases that opinion upon his belief that if ObTape was the source of the infection, plaintiff would have suffered a bi-lateral infection on her right thigh immediately and that the spread would involve both thighs. Plaintiff notes that, according to the literature Dr. Ballon-Landa uses as references, single thigh involvement is universally found. Further, this literature describes instances of significant post-implant delay before presentation of necrotizing fasciitis. The Court agrees with defendant that Dr. Ballon-Landa's opinion is not rendered unreliable by the instances of necrotizing fasciitis with suburethral slings involving a single thigh. Indeed, Dr. Ballon-Landa in his expert report notes that the same bacteria that found in plaintiff's left leg wound after a surgical procedure performed in 2006 was found in her right groin in December 2007 when the vaginal erosion was diagnosed.

Plaintiff also argues that Dr. Ballon-Landa relies too much on his own experience, rather than that of the literature. In formulating his opinion, Dr. Ballon-Landa relied upon multiple microbiological reports, plaintiff's medical chronology and medical records. There is no dispute that Dr. Ballon-Landa is qualified as an infectious disease specialist. Further, it is undisputed that an expert may draw conclusions from a set of observations based on extensive and specialized



experience. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999). A medical doctor does not need to have treated the specific disease at issue to opine on medical matters relating to that condition. *Kruszka v. Novartis Pharm. Corp.*, 28 F. Supp. 3d 920, 927 (D. Minn. 2014) (citing *Dittrich-Bigley v. Gen-Probe, Inc.*, Civil No. 11-1762, 2013 WL 3974107, at \*7 (D.Minn. July 31, 2013)). Dr. Ballon-Landa has extensive experience in the field of infectious diseases and he draws his conclusions from a number of medical sources. Dr. Ballon-Landa does not need to have experience specifically treating infections arising from ObTape to be able to opine on infectious diseases that have impacted individuals who have implanted ObTape devices. Accordingly, plaintiff's motion to exclude Dr. Ballon-Landa's opinion regarding plaintiff's bilateral thigh infection will be denied.

### **3. Timing of Initial Infection**

Lastly, plaintiff argues that Dr. Ballon-Landa's opinion about the onset of the ObTape infection is unsupported by the facts of this case, fails to account for contrary radiological evidence, and should be excluded as unreliable. In formulating his opinion that plaintiff's ObTape became infected with bacteria from the left groin wound source, Dr. Ballon-Landa relied upon medical records in determining that the transfer of bacteria from the left groin to the right groin following one of the surgical procedures was evidence that the ObTape was not initially infected during the first of plaintiff's surgical procedures. Dr. Ballon-Landa also noted the lack of symptoms of infection from the initial implantation of the ObTape. Dr. Ballon-Landa's opinions are based upon sufficient facts and data so as to be reliable. Plaintiff's complaint that Dr. Ballon-Landa only reviewed the deposition transcript of plaintiff's expert radiologist and not the radiology report

itself, may be asserted to discredit Dr. Ballon-Landa's expert testimony; however it is not pertinent to the issue of reliability which is the crux of Fed. R. Evid. 702 and the *Daubert* analysis. When there is a sufficient factual basis for an expert opinion to be both relevant and reliable questions of conflicting evidence must be left for the jury's determination. *Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 930 (8th Cir.2001). Accordingly, plaintiff's motion to exclude Dr. Ballon-Landa's opinion regarding when plaintiff's ObTape became infected will be denied.

**Marjorie Jeffcoat, D.M.D.**

Plaintiff seeks to exclude the opinions of Marjorie Jeffcoat, D.M.D., regarding: (1) the source of plaintiff's infection, (2) how the source bacteria traveled to the infected area, and (3) whether methamphetamine abuse and the consequences of "meth mouth" played a role in causing plaintiff's infection. [Doc. #107-1 and #107-3]. Plaintiff argues that Dr. Jeffcoat's opinions are not supported by sufficient facts or data as required by the Federal Rules of Evidence and are thus unreliable.

In her report, Dr. Jeffcoat opines that the bacteria cultured in plaintiff's thigh originated from her mouth based upon the dental records made available. Dr. Jeffcoat's conclusions are summarized as follows: (1) plaintiff had poor dentition, including rampant caries and severe periodontal disease, (2) her dental caries and periodontal disease were insufficiently treated, (3) she was resistant to antibiotics, (4) her poor dentition, trauma to the mouth, and susceptibility for infection caused bacteremia in the blood, and (5) that bacteremia infected her thigh. Further supporting this opinion, the plaintiff's thigh infection was polymicrobial and the thigh cultures consisted of bacteria commonly found in the mouth. Dr. Jeffcoat also

opined that plaintiff's ObTape was not the source of the bacteria infecting plaintiff's thigh, specifically noting that: (1) plaintiff's physicians did not find any connection between her thigh infection and the vagina or sling, (2) plaintiff exhibited no signs and symptoms of a vaginal or suburethral sling infection, including no discharge, bleeding, odor, or pain, and (3) if the bacteria had previously colonized plaintiff's sling, such as when it was implanted, the infection would manifest itself soon thereafter. This expert testimony would be useful to a jury in deciding whether the origin of the bacterial infection occurred in the mouth of the plaintiff or as a result of the suburethral sling as posited by the plaintiff. As such, Dr. Jeffcoat's opinions are relevant to the claims in this case.

### **1. Oral Bacteria**

Plaintiff argues that Dr. Jeffcoat's opinion that the bacteria cultured in plaintiff's thigh originated from her mouth is speculation that is unsupported by facts or data. Dr. Jeffcoat reviewed plaintiff's dental records and dental history. She also considered plaintiff's history of resistance to antibiotics and the microbiology taken from the deep tissue of plaintiff's left upper thigh. Dr. Jeffcoat's opinion is based on evidence that the wound culture from plaintiff's thigh is comprised of bacteria commonly found in the mouth. Further, the medical literature presented by Dr. Jeffcoat confirms that the hematogenous spread of oral bacteria is possible. The standard in *Daubert* calls for the liberal admission of expert testimony. *Johnson v. Mead Johnson & Co., LLC*, 754 F.3d 557, 562 (8th Cir.2014). Accordingly, the Court finds that Dr. Jeffcoat's opinions with regard to the origination of the bacteria are supported by sufficient facts.

The plaintiff also argues that Dr. Jeffcoat's opinion that bacteria in the mouth can lead to a large abscess in the thigh is unsupported by facts or data but instead relies upon mere speculation. In making this conclusion, Dr. Jeffcoat relied upon her personal experience witnessing the spread of oral bacteria to distant body sites in her dental patients. Dr. Jeffcoat has extensive experience observing the spread of oral bacteria to distant body sites and has specifically studied the spread of oral bacteria. Dr. Jeffcoat has specifically treated the hematogenous spread of oral infections in her patients and has studied and treated thousands of young women. Dr. Jeffcoat's research specifically studies the relationship between oral and systemic disease. Dr. Jeffcoat also reviewed and provided medical literature stating that microorganisms, such as bacteria, could be spread through the body through the bloodstream. The records Dr. Jeffcoat relied upon along with her background researching these issues provide a sufficient factual background under *Daubert* and Federal Rule of Evidence 702. See *Ayers Oil Co. v. American Business Brokers, Inc.*, 2010 WL 2990113, at \*4 (E.D.Mo. July 27, 2010) (holding opinions were admissible based on the expert's "extensive experience" despite the absence of objective testing or peer review; stating, "the four *Daubert* factors cannot be applied to every expert in every case, and in certain fields, experience in the industry is the predominant, if not sole, basis for reliable expert testimony").

Alternatively, plaintiff asks that Dr. Jeffcoat's testimony be limited to the opinion that a mouth infection is a "possible cause" of plaintiff's thigh infection. The Court does not believe such a limitation is either appropriate or necessary. Plaintiff will have ample opportunity at trial to challenge Dr. Jeffcoat's opinions and the factual bases upon which they rest through cross-examination and the presentation

of contrary evidence at trial. After review of Dr. Jeffcoat's expert report and deposition testimony, the Court finds that there are sufficient facts and data to support her opinion that the bacteria from plaintiff's thigh originated from her mouth and was transferred to her thigh. Accordingly, plaintiff's motion to exclude or limit Dr. Jeffcoat's opinion that oral bacteria is the cause of plaintiff's infection will be denied.

## **2. Methamphetamine Use**

Plaintiff next moves to exclude any testimony by Dr. Jeffcoat regarding methamphetamine usage. In her deposition, Dr. Jeffcoat testified that methamphetamine use was potentially the cause of plaintiff's dental issues. No methamphetamine-related opinions were included in either her Rule 26 report or her subsequent declaration. [Doc. #107-2, 107-3]. Dr. Jeffcoat noted that she was unable to diagnose plaintiff with "meth mouth" because she had not seen or observed plaintiff personally and that she was merely speculating.

In its response to the motion, defendant states that Dr. Jeffcoat's opinions concerning the cause of plaintiff's thigh infection does not depend on whether plaintiff abused methamphetamines. Defendant further states that Dr. Jeffcoat will not offer testimony at trial that plaintiff suffered from meth mouth. Based on these representations, the plaintiff's motion to exclude testimony by Dr. Jeffcoat about methamphetamine usage is moot.

### **Ruby Skinner, M.D.**

The defendant offers Dr. Skinner as an expert witness to testify that plaintiff's infections did not originate from her ObTape implant. [Doc. #114-1, #114-3]. Dr. Skinner opines that plaintiff's infection resulted from trauma to her

left thigh and groin area. Plaintiff asserts that Dr. Skinner's opinions exceed the bounds of her qualifications and are founded on insufficient facts and unreliable methodology.

Dr. Skinner is certified by the American Board of Surgery in general surgery and critical care and serves as Chief of the Division of Trauma and Medical Director of the Surgical Intensive Care Unit at Kern Medical Center in Bakersfield California. Dr. Skinner has practiced for thirteen years and has treated over one-hundred patients with severe necrotizing soft tissue infections. Dr. Skinner was educated at Spelman College and received her medical degree from the Boston University School of Medicine; she then did her post-doctoral training at the University of California-Davis and the University of Pennsylvania. Dr. Skinner has also published extensively in the area of acute care surgery and surgical critical care, including a paper published regarding her surgical experience with necrotizing fasciitis.

In her expert report and deposition, Dr. Skinner identified the reasons for her opinion that the ObTape was not the cause of plaintiff's infection: (1) plaintiff had no local vaginal symptoms when she was treated for her initial thigh infection, (2) the CT scan during her initial admission in 2005 showed no involvement of the obturator or pelvic area, (3) plaintiff's left thigh wound initially healed and plaintiff was recovering well; and (4) plaintiff had no vaginal symptoms when the left thigh infection recurred until after the infection spread to the right side. Dr. Skinner also identified several indicators that plaintiff's infection originated in her upper body and spread to her thigh, including recurrent dental infections, upper respiratory infections and trauma to plaintiff's left thigh before her initial admission.

Dr. Skinner's opinions and testimony would be relevant to a fact finder as they go to the determination of the source and the cause of the necrotizing fasciitis in plaintiff's thigh. Also, Dr. Skinner considered the medical records related to plaintiff's vaginal sling procedure, the medical records related to her initial left thigh necrotizing fasciitis, and the medical records related to subsequent hospitalizations and operations following the initial infection, thus grounding her testimony in both facts and data.

### **1. Prior trauma**

In her deposition, Dr. Skinner testified that necrotizing fasciitis is sometimes, but not always, preceded by a history of trauma. Contrary to plaintiff's assertions, Dr. Skinner did not speculate that plaintiff had suffered trauma to her left thigh during an accident at a water park.

Plaintiff also points out that Dr. Skinner could not rule out necrotizing fasciitis as the cause of plaintiff's pain prior to her diagnosis. However, "[p]roponents of expert testimony need not demonstrate that the assessments of their experts are correct, and trial courts are not empowered to determine which of several competing scientific theories has the best provenance." *Kuhn v. Wyeth, Inc.*, 686 F.3d 618, 625 (8th Cir.2012) (quoting *Milward v. Acuity Specialty Prods. Grp.*, 639 F.3d 11, 15 (1st Cir.2011)). Dr. Skinner's inability to rule out necrotizing fasciitis as the source of plaintiff's pain presents a factual dispute rather than an issue going to Dr. Skinner's reliability. As a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination. *Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 929–30 (8th Cir.2001) (citing *Hose v.*

*Chicago Northwestern Transp. Co.*, 70 F.3d 968, 974 (8th Cir.1996)). Dr. Skinner testified that in her experience as a critical care surgeon, necrotizing fasciitis does not always involve a history of trauma, but that the thigh trauma is an explanation for why the infection was located in plaintiff's thigh. Only if the expert's opinion is so fundamentally unsupported that it can offer no assistance to the jury must such testimony be excluded. *Id.*

Here, Dr. Skinner is qualified by her experience with regard to necrotizing fasciitis to opine about the potential causes of the infection. Dr. Skinner has articulated her opinions on the basis of a review of plaintiff's medical records and history and ultimately grounded her opinion in a review of the facts and data available. Accordingly, the motion to exclude her testimony on this issue will be denied.

## **2. Blood-Borne Spread**

In her expert report, Dr. Skinner states that plaintiff had a "history of chronic dental infections, and a recent history of an upper respiratory infection that are potential sources" for the bacteria found in her thigh. [Doc. # 114-1]. Plaintiff argues that Dr. Skinner's claim that she had a "recent history" of respiratory infection is a mischaracterization, because the infection occurred almost six months prior to the necrotizing fasciitis. Plaintiff also argues that the medical records which show that her blood cultures were negative for blood borne infection are inconsistent with Dr. Skinner's opinion that plaintiff's thigh infection resulted from "hematogenous [blood-borne] spread." Plaintiff's arguments present factual challenges to the expert's opinion—they do not present a justification for excluding



the testimony as unreliable. Dr. Skinner's opinion regarding hematogenous spread as possible cause of plaintiff's necrotizing fasciitis will be denied.

### **3. Mesh Complications**

The plaintiff also argues that Dr. Skinner is not qualified to opine about mesh complications. Dr. Skinner offered the opinion that ObTape was not the cause of plaintiff's necrotizing fasciitis. Dr. Skinner specifically opined that the "infection originating from the synthetic mesh was highly unlikely given the absence of symptoms in the vaginal region and perineum, prior to the development of the left thigh infection." [Doc. #114-1]. Plaintiff argues that Dr. Skinner has no experience in urology, gynecology, urogynecology, vaginal mesh, or complications related to slings. Rule 702 of the Federal Rules of Evidence requires that witnesses are qualified by "knowledge, skill, experience, training or education." Fed. R. Evid. 702.

In her deposition, Dr. Skinner acknowledged that she had no experience with vaginal mesh or with complications or infections relating to suburethral slings. However, Dr. Skinner is an expert on necrotizing fasciitis and she has extensive experience treating patients with the same condition as plaintiff. While deriving conclusions regarding the complications of transvaginal mesh is outside of her area of expertise, diagnosing necrotizing fasciitis is not. Because the cause of the necrotizing fasciitis is at issue, her experience and background with necrotizing fasciitis qualifies to opine as to the cause. Furthermore, the standard in *Daubert* calls for the "liberal admission" of expert testimony. *Johnson*, 754 F.3d at 562. Accordingly, the plaintiff's request to exclude Dr. Skinner's opinion that the mesh was not the source of plaintiff's infection will be denied.

## **B. Plaintiff's Motion to Enforce the MDL *Daubert* Orders**

Plaintiff moves to enforce prior *Daubert* orders [Doc. #112] entered by the MDL court regarding expert witnesses Drs. Arnold Lentnek, William Hyman, and Ahmed El-Ghannam, whose opinions and testimony defendant seeks to exclude.

To prevent inconsistent pretrial rulings on the admissibility of expert testimony, it is only in "exceptional cases, [that] the federal or state court to which an MDL case is transferred or remanded may revisit a transferee court's decision." *Deutsch v. Novartis Pharm. Corp.*, 768 F. Supp. 2d 420, 429 (E.D.N.Y. 2011) (citing *Manual for Complex Litigation* (4th) § 20.133 ("Although the transferor judge has the power to vacate or modify rulings made by the transferee judge, subject to comity and 'law of the case' considerations, doing so in the absence of a significant change of circumstances would frustrate the purposes of centralized pretrial proceedings.")). Reversing or otherwise undermining the decisions by the MDL court could lead to the type of inconsistent pretrial rulings that Congress sought to avoid, and therefore frustrate the very purpose of consolidation. *Id.* The objective of MDL transfer is to eliminate duplication in discovery, avoid conflicting rulings and schedules, reduce litigation cost, and save the time and effort of the parties, the attorneys, the witnesses, and the courts. *Manual for Complex Litigation* (4th) § 20.131. In circumstances, where causation issues predominate, it may be appropriate for the transferee court in an MDL proceeding to conduct a *Daubert* hearing on general causation issues, leaving specific causation issues for the transferor courts on remand. *Manual for Complex Litigation* (4th) § 22.87. Centralization for pretrial proceedings as occurs with MDL is specifically necessary to prevent inconsistent pretrial rulings on *Daubert* issues. *See In re Viagra*

(*Sildenafil Citrate*) *Prod. Liab. Litig.*, No. MDL 2691, 2016 WL 1403304, at \*1 (U.S. Jud. Pan. Mult. Lit. Apr. 7, 2016); *In re: 100% Grated Parmesan Cheese Mktg. & Sales Practices Litig.*, No. 2705, 2016 WL 3190426, at \*2 (U.S. Jud. Pan. Mult. Lit. June 2, 2016). Furthermore, any reversal of the MDL court rulings would undermine the purpose of the Multi-District Litigation Act, which authorizes the coordinated and consolidated pretrial proceedings of civil actions involving one or more common issues of fact “for the convenience of parties and witnesses and [to] promote the just and efficient conduct of such actions.” 28 U.S.C. § 1407(a).

In the instant case, the MDL court conducted a *Daubert* hearing, after which it found that the methodology employed by Dr. Lentnek in researching the medical literature on which his opinions rested was “scientifically and medically appropriate and reliable.” [Doc. # 120-3, p. 4]. The methodology examined by the MDL court is the same methodology that defendant challenges here. Nevertheless, defendant argues that because Dr. Lentnek submitted an “Additional Supplemental Rule 26 Expert Report” this Court should revisit the MDL court’s *Daubert* ruling. While the receiving court has the power to vacate or modify rulings made by the MDL court, doing so in the absence of a significant change of circumstances would frustrate the purposes of centralized pretrial proceedings. *Manual for Complex Litigation* (4th) § 20.133. Courts must ensure that “any and all scientific testimony or evidence admitted is not only relevant, but reliable.” *Daubert v. Merrill Dow Pharms.*, 509 U.S. 579, 589 (1993). There appears to be no basis for finding that the supplemental report undercuts or invalidates the reliability of Dr. Lentnek’s expert testimony. Further, Dr. Lentnek testified at his May 26, 2015 deposition that his updated literature review did not change his original conclusions. [Doc. #109-5].

The addition of the supplemental report does not rise to the level of a significant change of circumstances which would necessitate this Court frustrating the purposes of centralized pretrial proceedings. Accordingly, the Court will uphold the MDL court's *Daubert* ruling with respect to Dr. Lentnek.

Plaintiff also seeks enforcement of the *Daubert* order entered by the MDL court permitting the testimony of Dr. El-Ghannam. The defendant separately moves to exclude and/or limit the testimony of Dr. El-Ghannam on the grounds that his testimony would be both unreliable and unhelpful. [Doc. #108]. The MDL court previously denied defendant's motion to exclude Dr. El-Ghannam's testimony, finding it sufficiently reliable. [Doc. #70]. Defendant has not presented any information to persuade the Court to deviate from the the MDL court's ruling with respect to Dr. El-Ghannam's general causation testimony regarding degradation. Although the Court will enforce the MDL court's ruling on Dr. El-Ghannam's general causation testimony, it will conduct an independent *Daubert* inquiry with respect to his testimony on issues of causation that are specific to this case.

Finally, the MDL court made no ruling with respect to Dr. Hyman's opinions. Therefore, the plaintiff's motion will be denied as to Dr. Hyman

### **C. Defendant's Motions to Exclude**

Defendant seeks to exclude or limit the testimony of the following expert witnesses: Dr. Arnold Lentnek, Dr. William Hyman, Dr. Ahmed El-Ghannam, Dr. Vladimir Iakovlev, Dr. Farrin A. Manian, Dr. Doug Watanabe, Dr. Paul L'Ecuyer, and Kristin Kucsma [Doc. #108].

#### **Arnold Lentnek, M.D.**

Defendant moves to exclude the opinions and testimony of Dr. Arnold Lentnek on the grounds that they are unreliable. Dr. Lentnek's testimony is general causation testimony regarding ObTape and was previously allowed by the MDL court. As discussed above, this Court will enforce the MDL court's *Daubert* ruling. The defendant's motion is will be denied as to Dr. Lentnek.

**William Hyman, Sc.D., P.E.**

Plaintiff intends to present Dr. Hyman to offer opinions regarding the adequacy of the warnings accompanying ObTape and defendant's knowledge and state of mind. Dr. Hyman is a biomaterials specialist with over 45 years' experience in biomedical engineering. He holds a bachelor's degree in mechanical engineering from The Cooper Union, as well as a masters and doctorate of science degrees in engineering mechanics from Columbia University. He is Professor Emeritus of Biomedical Engineering at Texas A & M University and an Adjunct Professor of Biomedical Engineering at The Cooper Union. Dr. Hyman has educational and professional experience in biomedical engineering, biomaterials (specifically artificial implanted materials), mechanics, medical device design and system safety and, Food Drug Administration (FDA) regulations and has taught classes on those subjects for many years.

The defendant first challenges Dr. Hyman's qualifications to opine on the adequacy of the warnings accompanying ObTape. According to Dr. Hyman, the warnings were inadequate and the Instructions for Use (IFU) should have been changed multiple times. [Doc. #109-7]. Specifically, he concludes that defendant's warnings were:

"Inadequate in multiple ways including: (1) Failing to warn about the significant risk of serious and life threatening infections and abscesses;

(2) Failing to warn about the significant risk of erosion; (3) Failing to warn about the potential of additional surgeries; and (4) Failing to warn about the potential of chronic pain and dyspareunia.”

Hyman Expert Report at 10 [Doc. #109-7].

The defendant notes that Dr. Hyman has been precluded from offering these very opinions in the past, notably in *Cason v. C.R. Bard, Inc.*, where the court determined that he was not qualified to testify on the issue of warnings. 1:12-cv-1288, 2015 WL 9913809 (N.D. Ga. Feb. 9, 2015). The court in *Cason* noted that Dr. Hyman had never drafted an IFU and never reviewed the labeling of competitors. The device at issue in *Cason* was not ObTape or a similar transvaginal mesh device; however it was a device that is surgically implanted in the body. *Id.* Dr. Hyman has been permitted to testify in other Mentor vaginal mesh litigation; however his testimony concerned the alleged defective design of the device, not the adequacy of warnings. *See In re Mentor Corp. ObTape Transobturator Sling Products Liability Litigation*, No. 4:08-MD-2004 (CDL), 2016 WL 6138253, at \*5 (M.D. Ga. Oct. 20, 2016).

Whether or not a given warning is adequate depends upon the language used and the impression that it is calculated to make upon the mind of an average user of the product. *Robertson v. Norton Co.*, 148 F.3d 905, 907 (8th Cir.1998) (citing *Walton v. Sherwin-Williams Co.*, 191 F.2d 277, 285–86 (8th Cir.1951)). Questions of display, syntax, and emphasis are involved in evaluating a warning, or set of directions, and upon those matters plant pathologists and entomologists are not necessarily qualified to speak. *Id.* Expert knowledge of the product at issue does not necessarily provide the expertise on questions of display, syntax, and emphasis that the jury would expect from a bona fide warnings expert. *Id.* Plaintiff argues

that there is no requirement for experience designing medical device warnings before an expert can testify on the adequacy of warnings. However, Federal Rule of Evidence 702 provides a threshold requiring specialized knowledge specific to the expert's opinion. Fed. R. Evid. 702. Further, the party offering the expert testimony "must prove its admissibility by a preponderance of the evidence." *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 686 (8th Cir.2001) (citing *Daubert*, 509 U.S. at 592).

That is a threshold plaintiff is unable to meet. Dr. Hyman has no experience drafting an IFU for a medical device or the "complications" section of a device's product insert. He also has no experience in improving existing warnings or preparing alternative for medical devices or in reviewing the warning labels of competitor products. Plaintiff has not provided any relevant experience of Dr. Hyman with respect to warnings of any kind. Plaintiff argues that Dr. Hyman does not opine on the language, display, syntax, or emphasis of the warnings, but instead opines on deficiencies in the severity of the risks communicated in the IFU. Opining on the deficiencies of the severity of the risks communicated correlates directly with opining on the language, syntax and emphasis of the warning.

Plaintiff has failed to meet her burden to demonstrate by a preponderance of the evidence that Dr. Hyman is qualified to offer expert testimony on the adequacy of defendant's warnings. Accordingly, defendant's motion to exclude Dr. Hyman's opinions and testimony on the adequacy of defendant's warnings will be granted.

Defendant next challenges Dr. Hyman's opinions regarding defendant's knowledge, intent, and state of mind as improper expert testimony. Expert testimony on intent, motives, or state of mind of corporations has no basis in any

relevant body of knowledge or expertise. *Kruszka v. Novartis Pharm. Corp.*, 28 F. Supp. 3d 920, 937 (D. Minn. 2014) (quoting *Deutsch v. Novartis Pharm. Corp.*, 768 F. Supp. 2d 420, 442 (E.D.N.Y. 2011)). The question of corporate motive, intent, knowledge or state of mind is one for the jury, not for an expert. *In re Baycol Prod. Litig.*, 532 F. Supp. 2d 1029, 1069 (D. Minn. 2007). Here, plaintiff acknowledges that Dr. Hyman's statements regarding defendant's knowledge of the defects associated with ObTape are based on the corporate documents that Dr. Hyman reviewed. Recitation of defendant's own corporate documents does not fall within the purview of expert testimony under Federal Rule of Evidence 702. Plaintiff argues that Dr. Hyman filters the corporate documents through his experience in medical device design and system safety and FDA regulations, and that that combination of facts and scientific expertise will help the trier of fact. While that may be true, it misses the point. What Dr. Hyman proffers is his opinions on specific information available to defendant, defendant's actions in response to that information, and the ways in which that response fell below the standard of care for a medical device company. The points plaintiff argues do not go to defendant's corporate knowledge, intent, or state of mind. "The jury should hear and/or see first-hand any relevant evidence pertaining to the defendant's intent." *Cason v. C.R. Bard, Inc.*, No. 1:12-CV-1288-MHS, 2015 WL 9913809, at \*13 (N.D. Ga. Feb. 9, 2015). "Then the jury, not the witnesses, should consider the facts and make its own determination regarding [d]efendant's intent." *Id.* Dr. Hyman is qualified to give his opinion as to the ways in which defendant's response fell below the standard of care for a medical company. However, he cannot opine specifically on the defendant's knowledge, intent or state of mind as that is not the role of an



expert witness. Accordingly, defendant's motion to exclude Dr. Hyman's opinions and testimony on defendant's knowledge, intent, and state of mind will be granted.

**Ahmed El-Ghannam, Ph.D.**

Dr. El-Ghannam opines that the thermal bonding process by which ObTape fibers are melted together causes ObTape to degrade after implantation. [Doc. #109-17]. In reaching his conclusions, Dr. El-Ghannam examined segments of degraded ObTape that had been explanted from several plaintiffs in the MDL proceeding and conducted tests on ObTape exemplars provided by defendant. In addition, he reviewed defendant's internal documents regarding ObTape, as well as a variety of peer-reviewed articles regarding polypropylene mesh products. Dr. El-Ghannam observed degradation of ObTape when he viewed the explanted samples with a scanning microscope. Based on these tests, Dr. El-Ghannam concluded that ObTape had an unacceptable level of degradation, and opined that ObTape's unique thermal bonding process caused the degradation of the tape *in vivo*. Dr. El-Ghannam also noted that a different process, heat extrusion, is widely used and is not known to cause degradation. Dr. El-Ghannam further opined that any polypropylene that degraded to the same extent as ObTape would be unsuitable for implantation. Dr. El-Ghannam's opinion is that any product with a propensity to degrade as ObTape did is too dangerous to be used as a permanent implantable device because of that propensity to degrade. Dr. El-Ghannam stated that implantable material such as ObTape should not degrade inside the body, which, he noted, defendant's own internal documents confirm. The Court finds Dr. El-Ghannam's general causation opinions to be sufficiently reliable.

The defendant argues that Dr. El-Ghannam's opinions and testimony will not be helpful to the trier of fact because they are untethered to any specific causation opinions offered in this case. Dr. El-Ghannam's degradation theory is based upon the premise that *in vivo* degradation creates toxic byproducts that kills cells and tissue, causing adverse clinical effects. In his expert report, Dr. El-Ghannam cites to a number of scientific articles supporting his theory that *in vivo* degradation of ObTape could cause harm to women who have been implanted with the product. Defendant has presented no scientific basis for disputing Dr. El-Ghannam's conclusions or the scientific literature upon which they are based. Although the district court's gatekeeping function includes an analysis of the reliability of scientific evidence, neither Rule 702 nor *Daubert* requires that an expert opinion resolve an ultimate issue of fact to a scientific absolute in order to be admissible. *Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 929 (8th Cir.2001). The only question relevant to the admissibility of the scientific evidence is whether it is sufficiently reliable and relevant to assist the jury's determination of a disputed issue. *Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 929 (8th Cir.2001) (citing *Daubert*, 509 U.S. at 594–95). Here, Dr. El-Ghannam's opinion on toxic byproducts is sufficiently reliable and relevant based upon the scientific literature on which he rests his conclusions. Accordingly, defendant's motion to exclude Dr. El-Ghannam's toxicity hypothesis is will be denied.

Defendant also argues that because none of plaintiff's specific causation expert cites Dr. El-Ghannam's general causation opinion as support for their specific causation opinion with regard to plaintiff, his opinion would not be helpful in assisting the jury in determining whether ObTape caused plaintiff's injuries. Dr. El-

Ghannam's opinion concerns the degradation of ObTape and the adverse medical consequences of degradation. His conclusions were reached after testing and analysis of explanted and unimplanted ObTape devices and have support in the literature. "As long as the expert's testimony is supported by relevant scientific literature, it should be tested by the adversary process with competing expert testimony and cross-examination, rather than excluded by the court at the outset." *Johnson v. Mead Johnson & Co., LLC*, 754 F.3d 557, 561 (8th Cir.2014) (citing *Daubert*, 509 U.S. at 590, 596); see also *In re St. Jude Med., Inc. Silzone Heart Valves Prod. Liab. Litig.*, 493 F. Supp. 2d 1082, 1088 (D. Minn. 2007) (permitting an expert witness to testify generally about a product when the expert had knowledge and experience of the product and bases his opinion on relevant scientific literature). The court cannot at this time conclude that Dr. El-Ghannam's opinion on this matter would be completely unhelpful to the jury. See *Clark v. Heidrick*, 150 F.3d 912, 915 (8th Cir.1998) (explaining that "doubts regarding whether an expert's testimony will be useful should generally be resolved in favor of admissibility"). Accordingly with respect to Dr. El-Ghannam specific causation opinions, the defendant's motion will be denied.

**Vladimir Iakovlev, M.D.**

Dr. Iakovlev is a board-certified anatomical pathologist who has been designated as an expert witness by the plaintiff to offer general- and case-specific causation opinions in his field as a pathologist. He opines that ObTape can degrade – and, in plaintiff's case, did degrade – to cause adverse clinical effects. Dr. Iakovlev is an anatomical pathologist and director of cytopathology at the Department of Laboratory Medicine at St. Michael's Hospital in Toronto, Canada.

Dr. Iakovlev annually examines approximately 4,000-5,000 cases of explanted pathology specimens, reviews the available clinical information related to the patient, and reaches conclusions about the cause of a patient's symptoms. Dr. Iakovlev has examined over 230 different polypropylene mesh explants; 150 of which were transvaginal mesh explants samples. Of the 150 transvaginal mesh explant samples, Dr. Iakovlev estimates that sixty percent were transvaginal mesh slings. The explanted mesh types included a number of different designs developed by a number of different manufacturers. Dr. Iakovlev's data pool of mesh explant samples contains specimens of patients from St. Michael's Hospital, cases sent from outside hospitals, as well as potential and active litigation cases. While reviewing the clinical records of the plaintiff, Dr. Iakovlev looked for events and symptoms with temporal relationship to mesh placement, alteration, or excision as well as symptoms or procedures anatomically related to urogenital area and the mesh.

The defendant has moved to exclude both of Dr. Iakovlev's degradation opinions which separately detail his general and case specific causation opinions. First, defendant argues that Dr. Iakovlev's general causation opinions regarding degradation are unreliable because his opinions are not based on a reliable methodology. Defendant also notes that Dr. Iakovlev's degradation opinions have been excluded 28 times in mesh litigation. Dr. Iakovlev purports to offer general causation opinions on morphological findings associated with ObTape based on his evaluation of "over 230 different polypropylene mesh explants," including a mixture of hernia meshes, pelvic organ prolapse devices, and mesh slings. [Doc. #109-16]. However, his review is not specific to ObTape and was formulated for expert testimony in other litigation. [Doc. #109-23]. Also, Dr. Iakovlev acknowledges

that only some of the general opinions in his expert report are actually applicable to ObTape.

Further, of the 230 different polypropylene mesh explants Dr. Iakovlev reviewed, only four were samples of explanted ObTape. The samples were provided by plaintiff's counsel for purposes of litigation. Under the Eighth Circuit's *Daubert* analysis, the district court is guided to look skeptically when expert opinion is developed for the sole or primary purpose of litigation. *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 687 (8th Cir.2001). Dr. Iakovlev does not know how the samples were selected for his review, and there are no assurances that plaintiff's counsel did not opportunistically choose samples while ignoring others that might have weakened or disproved their theory of the case. Also, while eight ObTape samples were provided, Dr. Iakovlev reported a review of only four of them. There is no explanation of how the samples were selected for review or why all eight were not reviewed. Plaintiff has made no showing that reviewing only four explants is reliable using scientific methods. The Court finds Dr. Iakovlev's general causation opinions unreliable, and the motion to exclude them will be granted.

Defendant also challenges Dr. Iakovlev's specific causation opinions as unreliable. Dr. Iakovlev opines that the defective nature of plaintiff's ObTape in 2005 caused it to "harbor bacteria," leading to a serious infection of her left thigh through a sinus tract that allowed the infection to travel from the sling to her left thigh. [Doc. #109-31]. In formulating his opinion with respect to plaintiff, Dr. Iakovlev fully incorporated the opinions in his general causation report and separately reviewed the clinical records of plaintiff. Because the Court finds that the expert's opinion is unreliable with respect to general causation, it is

unnecessary to address defendant's arguments with respect to specific causation. *Glastetter v. Novartis Pharm. Corp.*, 107 F. Supp. 2d 1015, 1045 n. 29 (E.D. Mo. 2000), *aff'd*, 252 F.3d 986 (8th Cir.2001). Accordingly, defendant's motion to exclude the specific causation opinions of Dr. Iakovlev will be granted.

**Farrin A. Manian, M.D.**

Plaintiff identified Dr. Farrin A. Manian as an expert expected to testify at trial to provide differential diagnoses for the specific causation of plaintiff's injuries as a result of the implantation and subsequent infection of the ObTape suburethral sling. Dr. Manian is a medical doctor, board certified in Internal Medicine and Infectious Diseases. He has been practicing for over 30 years, including 27 years as Chief of Infectious Diseases and Hospital Epidemiologist at Mercy Hospital in St. Louis.

After conducting a differential diagnosis in this case, Dr. Manian gives his expert opinion that plaintiff's necrotizing fasciitis was caused by a group of bacteria seeding the ObTape at implementation. Dr. Manian opines that plaintiff's soft tissue infections, including her initial bout of severe necrotizing fasciitis, was a result of bacterial invasion of the ObTape with its subsequent spread to surrounding tissues with episodic flare-up of infections within her left and right thighs until the entire ObTape was removed. [Doc. #109-9]. In forming this opinion, Dr. Manian relied upon medical records from: (1) Platinum Surgical Care, (2) Barnes-Jewish Hospital, (3) Barnes-Jewish-West County, (4) Barnes-Jewish Center Home Care, (5) Body Aesthetic Plastic Surgery, (6) Barnes-Jewish Urology Clinic, (7) Jefferson Memorial Hospital, (8) Medical Arts Clinic, (9) Pain Management Center, (10) Parkland Health Center, (11) Dr. Paul L'Ecuyer's Consult Report. Dr. Manian also

reviewed dental records and considered whether plaintiff's history of tooth extractions and poor dental hygiene could have been the source of her infection. [Doc. #109-10]. After doing so, Dr. Manian maintained his opinion that vaginal flora was the primary source of plaintiff's infection, and that the bacteria gained access to her implanted prosthetic ObTape material by contiguous spread, not from a distant dental site.

A "differential diagnosis [is] a technique that identifies the cause of a medical condition by eliminating the likely causes until the most probable cause is isolated." *Id.* (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir.1999)). "[A] medical opinion about causation, based upon a proper differential diagnosis is sufficiently reliable to satisfy *Daubert*." *Bland v. Verizon Wireless, (VAW) L.L.C.*, 538 F.3d 893, 897 (8th Cir.2008).

Defendant argues that Dr. Manian did not perform a proper differential diagnosis because he failed to investigate and rule out all possible causes of plaintiff's infection. The Court disagrees. As discussed above, Dr. Manian considered the possibility that plaintiff's infection stemmed from her poor dental hygiene, given the fact that the bacteria cultured from plaintiff's thigh can also be found in the mouth. He also considered whether a soft tissue injury that plaintiff had sustained could have been the source of her infection. In his deposition, Dr. Manian explained in detail why, based on his experience and knowledge, he ruled out these other potential causes. [Doc. # 120-4]. Dr. Manian also relied upon CDC guidelines applicable to classifying surgical site infections, noting that with implantable devices, such as ObTape, "the recommendation is to go up to a year after surgery for diagnoses of surgical site infections." *Id.* at p. 274. Dr. Manian's

ultimate conclusion was supported by: (1) the fact that the infection was diagnosed within the timeline established by the CDC guidelines; (2) the type of bacteria found in the infected area were the same as that commonly found in the vaginal canal; and (3) the medical literature supporting similar type of infections occurring after “clean-contaminated” surgical procedures like the ObTape implantation. Dr. Manian conducted a proper differential diagnosis that is supported by his medical knowledge and experience, a review of the pertinent medical records, and an evaluation of the potential sources of the infection.

Defendant next argues that Dr. Manian’s opinion is unreliable because it rests on an unsupported assumption that the bacteria that allegedly infected the ObTape had lain dormant for several months after the implantation and until plaintiff presented with necrotizing fasciitis. Dr. Manian testified that “[i]t’s been well proven that if you have a prosthetic material, germs acquired at the time of surgery can lay dormant.” [Doc. # 109-6, pp. 80-81]. He further testified that infections “manifest themselves months or even a year longer after surgery” because the bacteria lay dormant. *Id.* at p. 81. Although Dr. Manian was unable to “point to a specific article” discussing how bacteria lay dormant for nine months, he was aware of case reports of infections caused by bacteria in the same class as that found in plaintiff that did not present until months after surgery. *Id.* Dr. Manian’s testimony and reports demonstrate that his opinion is not based solely on assumptions.

The Court finds that Dr. Manian’s expert opinion regarding the source of the plaintiff’s infection is reliable and, therefore, it will not be excluded.

**Doug Watanabe, D.D.S.**



The defendant seeks to exclude any testimony by Dr. Watanabe that plaintiff's infection was caused by ObTape. Although this is an opinion Dr. Watanabe expressed in his report, plaintiff states that he will not give this testimony at trial. Rather, Dr. Watanabe's expert testimony will be limited to his opinion that plaintiff's thigh and pelvic infections, abscesses, cellulitis, and necrotizing fasciitis were not caused by oral bacteria. Accordingly, the defendant's motion is moot.

**Paul L'Ecuyer, M.D.**

Defendant moves to exclude Dr. L'Ecuyer's opinion that an undiagnosed erosion of the ObTape sling caused plaintiff's infection. Defendant asserts that Dr. L'Ecuyer is not qualified to give this opinion, because he is not a urology specialist and he admitted that he did not know the symptoms of suburethral sling erosion. In his deposition, Dr. L'Ecuyer testified that he had no experience with suburethral erosions. [Doc. # 120-12, p. 158].

An expert witness must be qualified to assist the finder of fact. *Johnson v. Mead Johnson & Co., LLC*, 754 F.3d 557, 561 (8th Cir.2014). By his own admission, Dr. L'Ecuyer is not qualified to diagnose an erosion. The Court finds that his opinion that an erosion caused plaintiff's infection is based wholly on speculation. Therefore, defendant's motion to exclude it will be granted.

**Kristin Kucsma**

Plaintiff proposes to offer testimony from an economics expert, Kristin Kucsma, on the past, present, and future economic impact of plaintiff's injuries, including loss of earnings. [Doc. #109-32] Defendant argues that Ms. Kucsma's opinion is unhelpful and unreliable because it is based on the premise that plaintiff

is unable to work— a premise that plaintiff cannot establish. The Court agrees that the plaintiff must provide evidentiary support for the expert witness's opinion. However, the Court is not prepared to say that plaintiff will not be able to do so through the medical and employment evidence that she intends to offer and through her own testimony. Further, defendant offers no legal support for its contention that plaintiff cannot establish her inability to return to work without the testimony of a vocational or employment expert.

The defendant next seeks to exclude Ms. Kucsma's opinion on the value of the household services plaintiff provided before the ObTape surgery. Defendant first argues that the opinion is unhelpful because it addresses a category of damages that plaintiff is not entitled to recover. Under Missouri law, a plaintiff may recover damages for the loss of the ability to perform her own household services. *LaRose v. Washington Univ.*, 154 S.W.3d 365, 372 (Mo. Ct. App. 2004) (finding that the loss of ability to perform household services, or loss of ability to work, was properly included as an economic damage, recoverable by the plaintiff), *see also Collier v. Simms*, 366 S.W.2d 499, 500 (Mo. Ct. App. 1963) (holding that any physical inability of a housewife to perform domestic duties must necessarily mean a physical inability to work and labor and is a compensable item of damage to the wife, and not to her husband). Because the loss of household services is a category of damages which plaintiff is entitled to recover, Ms. Kucsma's opinion is relevant.

Defendant also argues that Ms. Kucsma's opinion is unreliable because it attaches a greater value to the loss of plaintiff's household services based on the assumption that plaintiff would be performing services for her dependent children until 2015, when plaintiff's youngest child turned 18. Defendant notes in

furtherance of its argument that plaintiff's ex-husband was given sole custody of their youngest son in November 2012 and there is no evidence that plaintiff continued to provide services to her son after that time. In her deposition, Ms. Kucsma testified that her opinion rests on evidence of the services plaintiff provided to her children that did not depend on them living with her. Additionally, plaintiff expects to offer evidence of her extensive involvement in her children's lives before her injury and her inability to continue that involvement after her injury

The Court concludes that the opinions of Ms. Kucsma on the issues of loss of earnings and loss of household services are both helpful and reliable. Therefore, the defendant's motion to exclude the opinions will be denied.

\* \* \* \* \*

For the reasons set forth above,

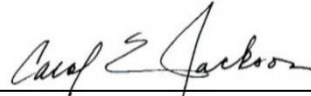
**IT IS HEREBY ORDERED** that the plaintiff's motion to exclude the opinions and testimony of defendant's expert Gonzalo R. Ballon-Landa, M.D., [Doc. #104] is **denied**.

**IT IS FURTHER ORDERED** that the plaintiff's motion to exclude the opinions and testimony of defendant's expert Marjorie Jeffcoat, D.M.D., [Doc. #106] is **granted in part and denied in part**.

**IT IS HEREBY ORDERED** that the plaintiff's motion to exclude the opinions and testimony of defendant's expert Dr. Ruby Skinner, M.D., [Doc. #113] is **granted in part and denied in part**.

**IT IS HEREBY ORDERED** that the plaintiff's motion to enforce *Daubert* orders [Doc. #112] is **granted in part and denied in part**.

**IT IS FURTHER ORDERED** that the defendant's motion to exclude certain testimony from plaintiff's expert witnesses [Doc. #108] is **granted in part and denied in part.**

A handwritten signature in cursive script, appearing to read "Carol E. Jackson", written in black ink.

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CAROL E. JACKSON  
UNITED STATES DISTRICT JUDGE

Dated this 30th day of December, 2016.